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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,134	01/28/2004	Donald J. Kerrish	61404-020	3590

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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,134	KERRISH ET AL.	
	Examiner	Art Unit	
	LAWRENCE E. CRANE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 25 & October 6, 2008 (responses)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-53 and 59-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53 and 59-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1-38 and 54-58** were previously cancelled, no claims have been newly cancelled, no claims have been additionally amended, no new claims have been added, and the disclosure has not been amended as per the responses filed August 25, 2008 and October 25, 2008. No supplemental or additional Information Disclosure Statements (IDSs) have been received as of the date of this Office action. Applicant has additionally provided a declaration filed October 6, 2008 under 37 C.F.R. §1.132 and signed by applicant Mssr. Kerrish. A rejection of claims **55 and 56** made in the previous Office action has been withdrawn as moot in view of the cancellation of the noted claims.

Claims **39-53 and 59-63** remain in the case.

Note to applicant: when a rejection or objection refers to a claim **X** at line y, the line number is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claim **39, 47, 49, 51 and 59-62** are objected to because of the following informalities:

In claim **39** at line 1, the term "ribavirin particules" is grammatically inconsistent with the term "mixture" at line 3. Examiner respectfully suggests that amendment of the first noted term to read -- ribavirin-containing particules -- would effectively address this issue. The same or a similar grammatical inconsistency may be found in claims **47, 49, 51 and 59-62**.

Appropriate correction is required.

Claims **39, 43, 47, 49, 51 and 59** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **39** the term "at least one excipient" renders the instant claim incomplete because the identity or the identities of the "excipient" has/have not been provided in the remainder of the claim, and because there is now no upper limit to the number of different excipients that may be present, i.e. a failure to provide adequately defined metes and bounds. See also claims **43 and 49**. See also claim **47** wherein the term "a binder, a filler and a disintegrant" has the same problems. See claim **51** which also fails to specifically identify the particular "excipient"

referred to generically therein and to claim **59** wherein the term "at least" introduces a problem with undefined upper limit (metes and bounds not adequately defined).

Applicant's arguments filed August 25, 2008 and October 6, 2008 have been fully considered but they are not persuasive.

Applicant has argued that the above rejection is inappropriate because the terms "excipient" and "binder" are terms well known to the ordinary practitioner and therefore not properly the subject of a rejection for indefiniteness, a view shared with the view expressed by applicant and declarant Mssr. Kerrish in the above noted declaration. Examiner respectfully disagrees. In examiner's view, the above rejection remains appropriate because the noted terms, when taken together with the terms "at least one" and "at least" and in the absence of a complete definition of the particular excipients and binders, continue to render the instant claims indefinite for failure to adequately define the metes and bounds of the claimed subject matter. In particular examiner is at a loss to understand how one or ordinary skill would know how to execute the claimed process if the particular binder(s) or excipient(s) to be incorporated therein have not been specified with adequate particularity.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thompson,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. §§1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with the application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, an registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **39-53 and 59-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-17*** of U.S. Patent No. **6,720,000** (PTO-892 ref. **I**). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to processes for making ribavirin-containing pharmaceutical compositions by a process involving wet granulation in the presence of a variety of pharmaceutical carriers and excipients, wherein the patented process is encompassed by the instant claimed process.

Applicant's arguments filed August 25, 2008 have been fully considered but they are not persuasive.

Applicant has again noticed and traversed this rejection, but has not responded either with an argument overcoming same or with the requested Terminal Disclaimer. Therefore, this rejection has been maintained.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **39-53 and 59-63** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Tam '097** (PTO-1449 ref. **A9**) in view of **Liebowitz et al.** (PTO-1449 ref. **A10**) and further in view of PTO-892 refs. **S (Rudnic) and T (Porter)**.

The instant claims are directed to a wet granulation/spheronization-spheronizing process of making a ribavirin-containing pharmaceutical composition using convention carriers and excipients.

Tam at column 4, lines 35-54 discloses multiple different variations of pharmaceutical compositions containing ribavirin as the active ingredient. **Tam** does not disclose any specific process details for the preparation of any pharmaceutical composition.

Liebowitz et al. is directed to ribavirin-containing pharmaceutical compositions which are fast dissolving and which include conventional carriers and excipients, and a process for

conversion of said composition into a fast-dissolving compacted capsule form. **Liebowitz et al.** does not disclose "spheronized" ribavirin-containing compositions or the subsequent coating thereof.

Rudnic (PTO-892 ref. **S**) beginning at column 1 of page 1646 discloses "Spheronization" which appears to be the same as applicant's "spheronizing." Rudnic does not disclose "spheronized" ribavirin-containing compositions.

Porter(PTO-892 refs. **T**) discloses the coating of pharmaceutical dosages forms and at page 1666 at column 1 lists 9 reasons for using this technology in the preparation of pharmaceutical compositions. Porter does not disclose "spheronized" ribavirin-containing compositions which have been further coated.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the disclosures cited because of the motivations provided by the Tam and Liebowitz references and because the variations claimed herein appear to be entirely conventional and to have not produced any unexpected results.

One having ordinary skill in the art would have been motivated to combine these references because Tam motivates the preparation of various pharmaceutical compositions and the remaining references provide details of how this may be accomplished in the manner claimed herein. In particular Liebowitz et al. provides a subsidiary motivation by disclosing the commonly used carriers and excipients. And lastly the chapters from Remington's Pharmaceutical Sciences provide details of how solid dosage forms may be prepared by various standard processes including spheronization, and how such pellets may be further process by addition of exterior coatings to effect rate of dissolution.

Therefore, the instant claimed process of producing ribavirin-containing pharmaceutical compositions using spheronized and optionally surface-coated pellets would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed August 25, 2008 and October 6, 2008 have been fully considered but they are not persuasive.

Applicant has argued that the **Liebowitz et al. '128** reference provides a factual basis for the instant claimed process claims, particularly by the assertion that speculation by **Liebowitz et al. '128** that "certain processing steps, including heat generated from a compaction step, would result in the formation of undesired polymorphic forms of ribavirin" is properly considered to be factual (reference to the Kerrish declaration at paragraph 8; made by applicant at page 3, lines 7-10 of the response of October 6, 2008). Examiner respectfully disagrees with applicant's analysis and particularly with applicant's conclusion. Examiner notes that **Liebowitz et al. '128** while speculating about the possibility that the heat generate by compaction of a mixture to form tablets might cause formation of undesired polymorphic forms (see column 2 at lines 31-35), but later concluded that this possible outcome had not occurred during execution of the disclosed process (see column 3 at lines 38-55). Therefore, examiner remains unconvinced by applicant's arguments, including the arguments made in the Kerrish declaration of October 6, 2008, and finds the reliance on the "conventional wisdom" asserted to reside in the **Liebowitz et al. '128** patent to be clearly misplaced. For these reasons the instant rejection has been maintained.

Examiner's arguments in made in response in the immediately preceding Office action have been repeated below to assist applicant's consideration of this Office action.

Applicant's arguments filed October 31, 2007 have been fully considered but they are not persuasive.

Applicant argues that the prior art does not teach the details of the instant claimed processes, an argument that appears to presuppose that the rejection was an anticipation rejection, not an obviousness rejection. Clearly the rejection was an obviousness rejection, and the obviousness standard does not require that every particular process detail be present in the cited art in order for the rejection to be properly made. More importantly, as taught by the **Billman** and **Rosicky** cases, when a composition including a known-in-the-art active ingredient, or in this case a method of making a composition wherein the active ingredient is well known in the art, unexpected results are necessary to establish that applicant is not merely claiming the result of a routine optimization of the prior art. While applicant can, and has, pointed out detailed differences between the instant claimed processes and the cited art, applicant has failed to provide any basis for concluding that the instant processes are

accompanied by any unexpected results. For this reason the instant grounds of rejection, amended to include new claims and exclude cancelled claims, has been maintained.

See also **Rudnic et al. '014** (PTO-1449 ref. A24, column 11 at lines 25-35); **Johannesson et al. '669** (PTO-1449 ref. **A30**, see claims ***13-16***); **Smith et al. '265** (PTO-1449 ref. **A26**, see pp 6, line 22 to page 7, line 17 and, formulation and use in process of making claims ***1-32***); **Witkowski et al. '216** (PTO-1449 ref. **A3**, see ointments, creams and topical solutions at columns 5-7); **Witkowski et al. '545** (PTO-892 ref. **C**, see ointments, creams and topical solutions at columns 5-7); **Witkowski et al. '771** (PTO-1449 ref. **A7**, see ointments, creams and topical solutions at columns 4-8); **Liebowitz et al. '594** (PTO-1449 **A11**, see columns 2 and 6-8); **Liebowitz et al. '252** (PTO-1449 **A12**, see columns 2 and 6-8); **Liebowitz et al. '032** (PTO-1449 **A19**, see columns 2 and 6-10); and **Liebowitz et al. '090** (PTO-1449 **A20**, see the Bowen declaration).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-**

0651. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

/L. E. C./

Examiner, Art Unit 1623

LECrane:lec
01/04/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623